

**RESULTS OF INVESTIGATION:** Examination showed that the article contained not more than 77 percent of the declared amount of phenobarbital.

**LIBELED:** 12-4-57, S. Dist. Ind.

**CHARGE:** 501(c)—the strength of the article, when shipped, differed from that which it purported and was represented to possess, namely, 1 grain of phenobarbital per capsule; and 502(a)—the label statement "Time-Sule Phenobarbital 1 Gr." was false and misleading.

**DISPOSITION:** 2-28-58. Default—destruction.

**5594. Tran-quiet tablets. (2 seizure actions). (F.D.C. Nos. 41374, 41375. S. Nos. 57-528 M, 77-788 M.)**

**QUANTITY:** 23 pkgs., each containing 6 ctns. enclosing a 30-tablet pill box, at St. Petersburg, Fla., and 43 ctns., each containing 1 pill box, at Miami, Fla.

**SHIPPED:** 9-19-57 and 10-19-57, from Cincinnati, Ohio, by Grandpa Soap Co. and C. S. Dent & Co., Div. Grandpa Soap Co.

**LABEL IN PART:** (Ctn.) "Dent's Tran-quiet 30 Tablets \* \* \* Each enteric-coated tablet contains: Theobromine Sodium Salicylate 100 mg. Acetylsalicylic Acid 3 gr. Acetophenetidin 2 gr. \* \* \* Distributed by C. S. Dent & Co., Cincinnati 2, Ohio."

**ACCOMPANYING LABELING:** Circulars reading in part "Personal for Women Only Take Free Leaflet" and package insert reading in part "to end those Blue Days \* \* \* Dent's Tran-quiet."

**LIBELED:** 1-23-58 and 1-27-58, S. Dist. Fla.

**CHARGE:** 501(c)—the strength of the article, when shipped, differed from that which it purported or was represented to possess since it contained a significantly lesser quantity of acetylsalicylic acid (aspirin) than the amount stated on the label; 502(a)—the label statement "Acetylsalicylic Acid 3 Gr." was false and misleading; 502(a)—the labeling of the article contained false and misleading representations that the article was an adequate and effective treatment for overcoming "nerve-racking pre-menstrual symptoms," overcoming effects such as nervous tension and irritability due to extra fluids which alter the water balance in the brain, overcoming pressure exerted by fluids on various parts of the body which result in a heavy, swelling feeling which robs one of looks and vitality and causes the face to become puffy, the hands and fingers to swell up, and causing pain in the back, legs, and breasts, eliminating "those terrible pressures that make you so uncomfortable, nervous and irritable at the onset of your period," and "preparing the body physiologically for the menstrual period"; and 502(e)(2)—the label of the article failed to bear the common or usual name of the active ingredient listed as acetylsalicylic acid, for which the common or usual name is aspirin.

**DISPOSITION:** 4-9-58 and 4-14-58. Default—destruction.

**5595. Del-Caps capsules and Del-Bardex capsules. (F.D.C. No. 41431. S. Nos. 34-042/3 P.)**

**QUANTITY:** 1 9,900-capsule drum, 1 49,900-capsule drum, 8 1,000-capsule btls., 7 500-capsule btls., and 42 100-capsule btls., of *Del-Caps*, and 1 25,000-capsule drum, 3 500-capsule btls., and 7 100-capsule btls. of *Del-Bardex* at Philadelphia, Pa.

**SHIPPED:** 11-5-57 and 11-27-57, from Rensselaer, N.Y., by Delmar Pharmacal Corp.

**LABEL IN PART:** (Drum) "Del-Caps 15 Timed Disintegration Capsule \* \* \* Each capsule contains 15 mg. of Dextro-Amphetamine Sulfate in a special base that provides for the disintegration of the contents throughout a period of 6-10 hours \* \* \* 3259" and "Del-Bardex #2 Timed Disintegration Capsule Each Capsule Contains Dextro-Amphetamine Sulfate 15 Mg. Amobarbital 100 Mg. \* \* \* Each capsule contains 15 Mg. of Dextro-Amphetamine Sulfate \* \* \* in a special base that provides for the disintegration of the contents throughout a period of about 6-10 hours \* \* \* 3100."

**RESULTS OF INVESTIGATION:** The capsules in the btls. had been repacked from the above-mentioned drums by the consignee after shipment.

Analysis showed that the *Del-Caps capsules* released 94 percent of their dextro-amphetamine sulfate content in 2 hours and that the *Del-Bardex capsules* released 80 percent of their dextro-amphetamine sulfate content in 2 hours.

**LIBELED:** 2-17-58, E. Dist. Pa.

**CHARGE:** 501(c)—the quality of the articles, when shipped, differed from that which they purported or were represented to possess in that they failed to disintegrate at a uniform rate over a 6- to 10-hour period; and 502(a)—the labels contained false and misleading representations that the dextro-amphetamine sulfate content of the articles would be released at a uniform rate over a 6- to 10-hour period.

**DISPOSITION:** 3-27-58. Default—destruction.

**5596. Del-Bardex capsules.** (F.D.C. No. 41491. S. No. 29-803 P.)

**QUANTITY:** 4 drums containing a total of 98,000 capsules at Jersey City, N.J.

**SHIPPED:** 12-17-57, from Rensselaer, N.Y., by Delmar Pharmacal Corp.

**LABEL IN PART:** "Del-Bardex # 2 Timed Disintegration Capsule Each Capsule Contains: Dextro-Amphetamine Sulphate 15 Mg. Amobarbital 100 Mg. \* \* \* disintegration \* \* \* period of about 6-10 hours."

**RESULTS OF INVESTIGATION:** Analysis showed that 90 percent of the dextro-amphetamine sulfate content of the article was released in 2 hours.

**LIBELED:** 3-28-58, Dist. N.J.

**CHARGE:** 501(c)—the quality of the article, when shipped, fell below that which it purported and was represented to possess since it failed to disintegrate at a uniform rate over a 6- to 10-hour period; and 502(a)—the label statement "disintegration \* \* \* period of about 6-10 hours" was false and misleading.

**DISPOSITION:** 4-28-58. Default—destruction.

**5597. S.C. red pyrilamine maleate tablets.** (F.D.C. No. 40995. S. No. 80-326 M.)

**QUANTITY:** 1 case containing 10,000 tablets at Minneapolis, Minn.

**SHIPPED:** 8-29-57, from St. Louis, Mo.

**RESULTS OF INVESTIGATION:** Examination showed that the article had a strong odor of acetic acid, contained large cracks in its coating due to bursting, and contained a significant amount of free salicylic acid.

**LIBELED:** 11-22-57, Dist. Minn.

**CHARGE:** 501(c)—the quality of the article, while held for sale, fell below that which it purported and was represented to possess since the tablet coatings were bursting and the aspirin was decomposing.

**DISPOSITION:** 1-6-58. Default—destruction.